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STONE CONROY

October 25, 2021

Via ECF

Honorable Zahid N. Quraishi, U.S.D.J.
United States District Court for the District of New Jersey
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street
Trenton, NJ 08608

***Re: Par Pharmaceutical, Inc., et al. v. Amneal EU, Limited, et al.
Civil Action No. 20-cv-18322 (ZNQ) (DEA)***

Dear Judge Quraishi:

This firm, along with Goodwin Procter LLP, represents Defendants in this litigation and we write on behalf of all parties to provide the Court with the requested status update (Doc. No. 27).

Amneal's applications before the FDA remain pending. Amneal does not have an estimate on when the FDA will approve the applications. As for the related suit in the District of Delaware, the Honorable Colm F. Connolly, Ch.U.S.D.J., held a trial on invalidity in July 2021 but has not issued a decision. No trial on the issue of infringement has been scheduled.

Plaintiff Par Sterile Products' NDA 204485/S-018 application for a post-approval supplement (the "PAS") to amend the NDA for Vasostrict® to add information relating to dosing by genotype is also pending before FDA. The application remains pending, but has not yet been approved.

The parties are available should Your Honor wish to discuss the matter in greater detail.

Respectfully submitted,

/s/ Rebekah R. Conroy
Rebekah R. Conroy

cc: Counsel of Record via ECF

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